K013177

DEC 1 9 2001

**Bonutti Research, Inc.**
**Multitak Suture Snap System**
**510(k) Premarket Notification**

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following information is submitted in accordance with the requirements of 21 CFR 807.92:

**Contact Person:** Patrick Balsmann, MS, RAC,
Director, Regulatory/Clinical Affairs & QA
Bonutti Research, Inc.,
P.O. Box 1367, Effingham, Illinois 62401
Phone: 217.342.3412, ext. 321

**Date Prepared:** September 21, 2001

**Proprietary Name:** Multitak Suture Snap System

**Common Name:** Resorbable Crimp

**Classification Name:** Fastener, Fixation, Biodegradable, Soft Tissue.

**Device Description:** The Multitak Suture Snap System is designed for approximating and securing soft tissue in arthroscopic and open surgical procedures. The resorbable poly-L-lactic acid crimp is ultrasonically welded to secure suture at the wound repair site and takes the place of tying arthroscopic and open surgical repair knots. The system consists of a generator that provides ultrasonic energy to a handpiece. The energy applied to the handpiece is used to ultrasonically weld a resorbable crimp and secure suture during general tissue wound repair. The resorbable poly-L-lactic acid crimp is gradually degraded into lactic acid and excreted as carbon dioxide and water.

**Intended Use:** The intended use of the Multitak Suture Snap System is in general soft tissue approximation and/or ligation. The system is indicated in securing soft tissue in arthroscopic and open surgical procedures where USP Size No. 2-0 through Size 2 nonabsorbable suture is used.



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**Predicate Device(s):** The Multitak Suture Snap System is similar in intended use and principle of operation to Axya Medical, Inc., Suture Welding System and Kit. Both systems use ultrasonic energy to secure suture without tying a knot. The Multitak Suture Snap System is also similar in intended use to Innovasive Devices, Inc., Y-Knot Suture Clip. Both systems use a two-piece crimp component to secure suture without tying a knot. The Multitak Suture Snap System resorbable crimp is similar to currently marketed poly-L-lactic acid devices including the Mitek BTB Absorbable (PLA) Cross Pin.

**Predicate Comparison:** Performance testing comparing the mechanical strengths of knotted nonabsorbable braided polyester suture to the same type of suture secured with the Multitak Suture Snap 2 Resorbable Crimp was conducted to demonstrate substantial equivalence. Genzyme Surgical Products, Inc., nonabsorbable suture was used as the predicate comparison device. Results of bench testing and an in vitro degradation study demonstrated no statistical difference in suture secured with the resorbable crimp and knotted suture. The results demonstrate that the Multitak Suture Snap Resorbable Crimp provides an alternative means to tying surgical knots with nonabsorbable suture.

**Submitted by:**

**Patrick Balsmann**
**Director, Regulatory/Clinical Affairs & QA**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Patrick G. Balsmann
Director, Regulatory/Clinical Affairs and QA
Bonutti Research, Inc.
P.O. Box 1367
Effingham, Illinois 62401

Re: K013177
Trade Name: Multitak Suture Snap System
Regulation Number: 878.4493; 888.3040
Regulation Name: Absorbable PGL Suture; Bone Anchor
Regulatory Class: II
Product Code: GAM; MAI
Dated: September 21, 2001
Received: September 24, 2001

Dear Mr. Balsmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Neil R.P. Ogden for CMW

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013177

Device Name: Multitak Suture Snap System

**Indications for Use:** The intended use of the Multitak Suture Snap System is in general soft tissue approximation and/or ligation. The system is indicated in securing soft tissue in arthroscopic and open surgical procedures where USP Size No. 2-0 through Size 2 nonabsorbable suture is used.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

MRO for CMW

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013177

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)